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TO RUEHC/SECSTATE WASHDC 7634
INFO RUEHRI/AMCONSUL RIO DE JANEIRO 3545
RUEHRG/AMCONSUL RECIFE 6013
RUEHSO/AMCONSUL SAO PAULO 8853
RUEHBU/AMEMBASSY BUENOS AIRES 4477
RUEHAC/AMEMBASSY ASUNCION 5844
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TAGS: ETRD ECON BR
SUBJECT: Brazilian Regulatory Agency Contemplates Increasing Barriers to Imported Medical Devices

¶1. (SBU) Summary. ANVISA, Brazil's FDA-equivalent, has published new regulations which require importers of medical devices to provide the agency with detailed foreign economic pricing data, along with it product registration or re-registration dossier, as a condition for market access. Companies will have to comply with this new requirement as of December 13. At the urging of U.S. exporters, Embassy officers have weighed in with ANVISA in an attempt to delay or modify this requirement - but to no avail. Given the inherent difficulties in providing such a complex package of data, we worry that this new regulation will hinder U.S. exports of medical devices to Brazil. According to USDOC statistics, in 2005 U.S. medical device and diagnostic manufacturers exported over US$ 400 million in products to Brazil. End Summary.

¶2. (SBU) On December 22, 2005 ANVISA first proposed a new technical regulation requiring the provision of economic (i.e., pricing) information when importers apply to register or reregister medical devices in Brazil. (Once a product is registered, it may remain on the market for five years.) During the public comment process, U.S. and Brazilian companies objected to the new regulation. Five Brazilian industry associations voiced their concerns to both ANVISA and the Ministry of Health. Notwithstanding their pleas, ANVISA has moved forward to finalize the decree. As of December 13, 2006, the regulation becomes effective and medical and diagnostic companies will be required to provide: 1) prices in ten other countries (Australia, Canada, Spain, USA, France, Germany, UK, Italy, Japan, and Portugal), 2) the potential number of patients that will use the product, 3) the contemplated price in Brazil, 4) the factory price and Brazilian distribution margins, 5) expected sales and publicity expenses, and 6) a list of substitute products, along with their prices.

¶3. (SBU) U.S. exporters view these requirements as impractical. Specifically, they note that: a) some of the requested data may not be available, b) even if it is, anti-trust considerations might prevent them from providing foreign prices, c) given differing national cost structures, foreign prices are not a good indicator, d) ANVISA has provided them with no assurances of data confidentiality, and e) ultimately this regulation could impede

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patient access to innovative medical technology.

¶4. (SBU) Comment. Concerned about the soaring cost of medical care, the Brazilians likely believe that they will be able to jawbone importers into lowering prices for their products if the GOB

has foreign reference prices in hand. Indeed, we've seen this type of behavior before. In 2005, the Ministry of Health used the threat of compulsory licensing to get two U.S. manufacturers to reduce their prices on key imported anti-aids pharmaceuticals. (Negotiations with a third U.S. pharmaceutical maker are still ongoing.) To make our case, Embassy plans to discreetly approach health sector policymakers in an effort to change some minds. Given Brazilian sensitivities to the thought of "foreign interference" a high-profile lobbying campaign would very likely prove ineffective. Accordingly, Embassy believes that a more low-key approach might yield greater results.

WILLIAMSON